PATENT

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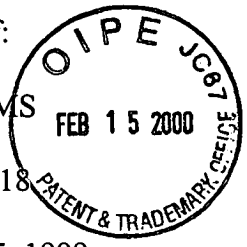

In re Application of:	)	
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Jonnie R. WILLIAMS	)	
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Serial No. 09/397,018	)	Group Art Unit: 1731
	)	
Filed: September 15, 1999	)	Examiner: Unknown
	)	
For: IMPROVED METHOD OF TREATING TOBACCO TO REDUCE NITROSAMINE CONTENT, AND PRODUCTS PRODUCED THEREBY	)	Atty. Dkt. No.: 04859.84703

INFORMATION DISCLOSURE STATEMENT, INCLUDING DISCUSSION OF REFERENCES IN SUPPORT OF PETITION TO MAKE SPECIAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The patents and documents listed on the attached PTO-1449 (six sheets), copies of which are enclosed, are relevant for the disclosures discussed below. This Information Disclosure Statement is being filed to support the accompanying Petition to Make Special Under 37 C.F.R. §1.102(d). The patents and documents were found in pre-examination searches and/or were cited in related applications. The attached patents and documents discussed below are deemed most closely related to the subject matter encompassed by the claims of the present application.

The subject matter of the subject application relates to tobacco products having reduced nitrosamine content and methods and apparatuses for preparing such tobacco products.

RELEVANCE OF THE REFERENCES

The following references are relevant for their respective disclosures discussed below:

Heljo U.S. Patent 2,758,603

Heljo describes applying radio frequency energy to already-cured tobacco. The electromagnetic energy has a frequency of 16 to 60 megacycles (MHZ) (column 2, lines 37-41), which is well below microwave frequencies (about 1,000 to 300,000 MHZ) as can be used in accordance with the present invention. The radio frequency energy used in Heljo is said to decompose harmful nitrogenous and other undesirable constituents which produce objectionable odors and tastes. The tobacco being treated is already dried (cured), which is known to contain significant levels of TSNAs. This is clearly evident from the disclosed moisture levels for the tobacco being treated. Heljo describes increasing the moisture content of the tobacco prior to applying high frequency energy (column 2, lines 29-37), typically to 18-25% (column 3, lines 5-10), which means that the original moisture content of the tobacco was substantially less, *i.e.*, the tobacco was dried. Although Heljo refers to the tobacco as "uncured," the term is used in a non-conventional sense because the tobacco is already dried at that stage.

Northway U.S. Patent 5,810,020

Northway discloses a process which is said to remove nitrogen-containing anions and tobacco-specific nitrosamines from tobacco products. Northway describes forming an extract from solid tobacco material using tobacco leaves, stems, or dust which have been ground or pulverized, (column 5, lines 54-55). The resulting tobacco extract is said to be separated from insoluble solid tobacco fibrous residue, (column 6, lines 19-21). An aqueous-immiscible organic solvent containing a crown ether is mixed with the aqueous solution containing soluble components from the tobacco material. The organic phase, containing a crown ether-cation-nitrate (or nitrate) complex, is separated from the aqueous phase containing the denitrified tobacco materials.

The denitrified tobacco material can be contacted with a trapping sink containing a select transition metal complex which is said to be readily nitrosated to form a nitrosyl complex, thereby removing tobacco-specific nitrosamines from the denitrified tobacco material (column 12, line 56 to column 13, line 7). The denitrified material then is returned to the insoluble solid tobacco fibrous residue (column 9, lines 28-31). The document provides no quantitative data on nitrosamine content in the tobacco product. Tobacco which has been treated with organic solvent is known to contain residual amount of solvent. *See, e.g.*, Stuhl U.S. Patent 4,821,747, which teaches that even when microwave treatment is used to evaporate residual solvent ("impregnant") from tobacco, some solvent remains in the tobacco product (column 5, lines 18-20).

Wiernik et al., "Effect of Air-curing on the Chemical Composition of Tobacco," Recent Advances in Tobacco Science, Vol. 21 at p. 56

Wiernik reports that Skroniowski tobacco subjected to air-curing in Poland was found to have a TSNA content of 0.2 μg/g. The Skroniowski tobacco described in Wiernik is Skroniowski Cienny L56, a dark air-cured (DAC) variety. *See* January 18, 2000, Declaration of Harold R. Burton, Ph.D., submitted herewith; *see also* "The *Nicotiana* Catalogue," Compilation of International Tobacco Germplasm Holdings, Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA), 1998. The relatively low nitrosamine content of the air-cured, Skroniowski tobacco is due to the tobacco having a low content of nicotine and other tobacco alkaloids, from which nitrosamines primarily are formed.

Andersen et al., Accumulation of 4-(N-Methyl-N-nitrosamino)-1-(3-pyridyl)-1-butanone in Alkaloid Genotypes of Burley Tobacco during Postharvest Processing: Comparisons with N'-Nitrosonornicotine and Probable Nitrosamine Precursors, Cancer Research Vol. 45, Nov. 1985, pp. 5287-5293. ("Anderson '85")

Anderson '85 describes the relationship of NNK, NNN, and their "probable precursors," *i.e.*, nitrate, nitrite, and alkaloids, as determined (a) after the growth of Ky 14 burley tobacco under

different shade conditions followed by air curing; and (b) during preparation of air-cured and homogenized-leaf-cured (HLC) burley tobaccos from conventionally-grown tobaccos of different alkaloid type. Anderson '85 reported *inter alia* that air-cured Ky 14 burley tobacco (middle leaf position on stalk) grown in 65% shade had an NNK content of 0.18 μg/g and an NNN content of 1.5 μg/g (Table 2, p. 5289). Air-cured and HLC tobaccos of different alkaloid types, when dried, were found to contain higher NNN and NNK levels (Table 1, p. 5289 and Table 4, p. 5291).

W.J. Chamberlain et al., Effects of Curing and Fertilization on Nitrosamine Formation in Bright and Burley Tobacco, Phytochemical Research Unit, USDA, Agricultural Research Service, Beitrage zur Tabakforschung International, Vol. 15, No. 2, April 1992 ("Chamberlain '92")

Chamberlain '92 describes the effects of nitrogen fertilization on alkaloid and nitrosamine levels in lamina of air-cured and flue-cured tobacco. At page 89, Table 1, Chamberlain '92 reports that air-cured KY 14 and G 28 tobacco which was grown in the absence of nitrogen fertilization had NNN contents of about 0.12 and 0.04 μg/g, respectively, and total TSNA contents of about 4.28 and 1.86 μg/g, respectively.

W.J. Chamberlain et al., Studies on the Reduction of Nitrosamines in Tobacco, Tobacco International, (1986) Vol. 188, No. 16, pp. 38-39 ("Chamberlain '86")

Chamberlain '86 reported a 76% reduction in the amount of NNN in flue-cured NC 2326 leaves by spraying ascorbic acid on harvested leaves (bottom of p. 38). Chamberlain '86 concluded that ascorbic acid had no effect in reducing NNN when sprayed on leaves that were still on the plant (p. 39 bottom of col. 1).

Shehad et al. U.S. Patent 5,023,376

Shehad describes reducing nitrosamine formation during reactions between secondary or tertiary amines and hydrogen peroxide to yield amine oxides, which are described as useful in personal hygiene preparations (column 1, lines 28-44). According to Shehad, nitrosamine formation

can be ameliorated by employing a selected range of alkyleneaminopoly(methylenephosphonic acid) compounds such as cyclohexane-1,2-diaminotetra(methylenephosphonic acid) (column 2, line 52 to column 3, line 17).

Beckett et al. U.S. Patent 5,431,175

Beckett describes providing proportional-integral-derivative (PID) control for controlling humidity or wet bulb temperature within a drying structure during curing and drying of tobacco or other agricultural products. A controller continuously controls the quantity or amount of air exhausted from the drying structure and the amount of air induced or brought into the drying structure, so as to compensate for dynamic changes within the material being cured and for outside environmental changes (column 2, lines 48-65). Beckett does not describe avoiding anaerobic conditions nor does the document address nitrosamine formation in tobacco.

Crump, III et al. U.S. Patent 5,335,590

Crump '590 discloses an apparatus for reordering or drying tobacco. The device has a plurality of chambers which are said to increase vertical flow through a packed bed of a conveyed product. The device also is said to avoid excessive mechanical resistance to rotation of the spiraling conveyor stack from an abundance of seal strips, to channel the air through the conveyor stack (column 5, lines 9-14). Crump '590 does not describe avoiding anaerobic conditions nor does the document address nitrosamine formation in tobacco.

Joubert et al. U.S. Patent 4,470,422

Joubert discloses a method and apparatus (barn) for curing tobacco employing circulating air to dry tobacco leaf. The apparatus includes temperature control means for maintaining a predetermined temperature or humidity difference between upper and lower zones inside the barn, which is said to avoid shock effects to the leaf (column 1, lines 59-64). The curing process is said

to depend on the state of the leaf and on conditions inside the barn, while not being influenced by ambient conditions (column 2, lines 1-6). Joubert does not describe avoiding anaerobic conditions during curing nor does the document address nitrosamine formation in tobacco.

Mitchell et al. U.S. Patent 4,212,634

Mitchell discloses a tobacco barn having a conventional forced air heating system including a fan and a gas ring burner (column 3, lines 61-66). The barn also has an auxiliary heating system which can be a wood or coal burning stove (column 2, lines 29-32). A temperature controller controls both heating systems to maintain a desired temperature within the barn during curing and drying (column 4, lines 33-64). The heated air generated by the conventional forced air system is directed by the fan into a heat exchanger of the auxiliary heating system and thereafter returned to the barn (column 5, lines 20-63). Mitchell does not describe avoiding anaerobic conditions during curing nor does the document address nitrosamine formation in tobacco.

Touton U.S. Patent 3,024,792

Touton '792 describes a tobacco curing apparatus in which the amount of air circulated is regulated in accordance with the total evaporation from the tobacco and is established so as to minimize reductions in tobacco temperature due to evaporative cooling (column 2, lines 45-50). After passing through the tobacco bed, the air is treated by a conditioning unit and recirculated. A portion of the damp air is replaced with fresh air to maintain the desired rate of evaporation (column 2, lines 61-65). Touton '792 does not describe avoiding anaerobic conditions during curing nor does the document address nitrosamine formation in tobacco.

Jünemann et al. U.S. Patent 5,791,353

Jünemann discloses a method for denitrating tobacco stem material. The tobacco stem material is described as having a moisture content of about 70% by weight, *i.e.*, uncured (column

2, lines 12-14). The nitrate-rich stem material is passed though a water bath and then through a region filled with steam, wherein nitrates contained in the stem material are said to dissolve in the water solvent. The denitrated tobacco stem material then can be blended with dry stem material (column 4, lines 12-35). Jünemann does not describe a cured tobacco product having reduced nitrosamine content.

Livingston U.S. Patent 4,836,222

Livingston '222 describes de-greening and coloring tobacco by subjecting the tobacco to air containing ethylene gas as a ripening agent. Livingston '222 discloses that the effects of ethylene are improved by exchanging the air within the curing barn 10-110 times per 24 hour period, which reduces carbon dioxide content and increases oxygen and nitrogen content (column 5, line 43 to column 6, line 55). Livingston '222 does not describe curing tobacco in an environment substantially free of combustion exhaust gases to produce cured tobacco having reduced nitrosamine content.

Moore, Jr. U.S. Patent 2,475,568

Moore, Jr. describes a process for curing bright-leaf tobacco. Moore, Jr. discloses drying yellowed leaves by drawing air from inside a shed housing an oil burner (*see* Fig. 1); heating the air to 100 to 120 or 130 °F; and forcing the heated air into the barn at about 4,000 cubic feet per minute (CFM). Drying the tobacco in this manner is said to increase the rate of drying without damaging the tobacco's cell structure (column 5, lines 15-41). Higher temperatures (above 120 or 130°F) are said to progressively deteriorate cell structure (column 5, lines 51-57). Moore, Jr. does not describe providing a curing environment substantially free of combustion exhaust gases, nor does the document address nitrosamine formation in tobacco.

Gaisch et al. U.S. Patent 4,709,710

Gaisch describes microorganisms which are said to reduce nitrate and/or nitrite content in a highly concentrated culture (column 1, lines 56-65). Tobacco to be treated is extracted with water to remove soluble nitrates and/or nitrites, and the aqueous extract is inoculated with the microorganism culture. Controlled anaerobic conditions are said to enhance reduction of nitrate and/or nitrite content. The microorganisms are removed by filtration, centrifugation, or the like, and the extract is reapplied to the tobacco material (*see, e.g.,* column 3, lines 1-14). Gaisch does not discuss nitrosamine content in cured tobacco.

Malik et al. U.S. Patent 4,685,478

Malik describes using microorganisms for reducing levels of nitrate and other nitrogen-containing compounds in tobacco extracts by microbial denitrification. High temperatures and thermophilic microorganisms are said to afford reduction of nitrate and other nitrogen-containing compounds via an anaerobic, dissimilatory, metabolic pathway (column 4, lines 47-55). Malik does not discuss nitrosamine content in cured tobacco.

Wilson U.S. Patent 3,664,034

Wilson '034 discloses a tobacco curing barn having air flow throttling damper members for selectively adjusting air flow during yellowing and drying (column 5, lines 30-32 and column 6, lines 53-71). A fresh air inlet also has a damper member to adjust the amount of air introduced to control relative humidity of the curing air (column 3, line 74 to column 4, line 15). Air flow is increased to 50-120 CFM during the later stages of stem and leaf drying (column 5, lines 22-32). Wilson '034 does not describe providing a curing environment substantially free of combustion exhaust gases, nor does the document address nitrosamine formation in tobacco.

Other Documents

The remaining documents listed on the enclosed form PTO-1449 have been considered but are believed to be no more relevant than those discussed above.

REMARKS

Applicant respectfully submits that none of the documents describes or suggests tobacco products comprising cured tobacco having nitrosamine content reduced by heating uncured tobacco with convection in an environment substantially free of exhaust gases or which otherwise is substantially non-anaerobic, *e.g.*, by maintaining a sufficiently high airflow to avoid anaerobic conditions, as set forth in claims 14 and 29-48. The resulting tobacco product is materially and substantially different than tobacco described in the documents discussed hereinabove. The documents also do not describe or suggest cured tobacco having contents of NNN, NAT+NAB, and/or NNK as specified in claims 21-25, or cured tobacco having a content of NAT, NAB, or NNK which is at least 50% by weight lower than the corresponding nitrosamine content in cured tobacco made from the same crop, *i.e.*, tobacco grown under the same conditions, as set forth in claims 15-19.

The method set forth in claims 1-13 and 50-52 and the apparatus set forth in claims 26-29 also distinguish each of the cited documents. None of the documents describes providing a tobacco curing environment substantially free of exhaust gases or otherwise controlling curing conditions to prevent an anaerobic environment, so as to reduce formation of TSNAs during tobacco curing.

In view of the Petition to Make Special submitted herewith, Applicant respectfully requests prompt review and consideration of the attached documents and this application.

Respectfully submitted,

Date: February 15, 2000

By: Paul M. Rivard

Paul M. Rivard
Registration No. 43,446

BANNER & WITCOFF, LTD.
Eleventh Floor
1001 G Street, N.W.
Washington, DC 20001-4597
(202) 508-9100